REMARKS

Claims 1-12 are currently pending in this application, with claims 13-24 having been withdrawn from consideration based on an election/restriction requirement. Claim 1 is an independent claim drawn to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric, with claims 2-7 depending therefrom, while claim 8 is an independent claim also drawn to a composition, with claims 9-12 depending therefrom.

Claims 1 and 3 stand rejected as being anticipated by the Majeed patent (U.S. Patent No. 5,861,415), while claim 5 stands rejected as being obvious over the Majeed patent in view of "Antioxidant Effects of Tea" or Applicants admission regarding the prior art. Claims 1-12 stand rejected as being obvious over the Oppenheim reference (WO 99/20289) in view of "Antioxidant Effects of Tea". In addition, claims 1-4 stand rejected under the doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,391,364 (sic) and over claim 1 of U.S. Patent No. 6,264,995.

With entry of the following remarks, Applicant respectfully submits that the claims are now in condition for allowance.

1. Summary of Interview

Applicants thank the Examiner for kindly meeting with

Applicants' attorney to discuss the claims and prior art in this case. At the interview, Applicants put forth that the claims are not anticipated, nor are they rendered obvious, by the Majeed patent and other cited prior art due to the differences in the extracts of the turmeric. The Examiner maintained her position, indicating that both extracts of turmeric would contain the curcuminoids of the structure at the top of column 2 of the Majeed patent. Applicants herewith reiterate their argument, and present further evidence in support of their position regarding the differences in extracts, such differences not being found in any of the cited prior art references.

2. Rejection of Claims 1 and 3

Under 35 U.S.C. 102(b)

The Examiner has rejected claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Majeed et al. (U.S. Patent No. 5,861,415, "the '415 patent") for the reasons set forth in the office action.

RESPONSE

Applicants respectfully traverse this rejection and request

reconsideration and withdrawal thereof.

To establish an anticipation rejection, every claimed element must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *See also*, MPEP § 2131. Applicants respectfully submit that the '415 patent does not teach every claimed element within the independent claim, and therefore also in the dependent claim, thereby failing to anticipate the claims.

Claim 1 is directed to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric. Applicants submitted during the interview with the Examiner that the '415 patent (as well as the other prior art patents) do not teach this combination. Applicants reiterate this position.

Attached herewith for the Examiner's consideration is a declaration under 37 CFR 1.132. The declaration is from Dr. Karl-Werner Quirin, a doctor in chemistry who has worked in the field of herbal extraction for over 18 years. Dr. Quirin is knowledgeable of the subject matter of the claims under consideration and with the prior art.

As is stated above, claim 1 is directed to a composition comprising a supercritical extract and a hydroalcoholic extract of

turmeric. According to Dr. Quirin's declaration, there are important differences between a supercritical extract of turmeric and a hydroalcoholic extract of turmeric. In paragraph no. 7 of the declaration, Dr. Quirin indicates that extraction by supercritical CO_2 results in an extract that contains mainly oily constituents, while an extract made by hydroalcoholic extraction results in a hydrophilic extract.

Dr. Quirin continues, in paragraph no. 8, by pointing out the properties of the supercritical extract. Namely, the supercritical extract is made up of about 70% steam volatile oily terpenes, of which 80% are turemerone isomers, with the remaining 30% of the extract being non-volatile lipids. Furthermore, Dr. Quirin indicates in paragraph no. 9 that the more polar curmuminoids are present in the supercritical extract in **trace amounts**. The curcuminoids are the molecules of the structure on the top of column 2 of the '415 patent. More particularly, curcumin is present in an amount of 0.15% by weight, with the other two isomers (demethoxycurcumin and bisdemethoxycurcumin) being practically undetectable in the supercritical extract. Thus, the supercritical extract of turmeric will effectively be devoid of the structure found on the top of column 2 of the '415 patent.

Still, even though the supercritical extract does not contain

the curcuminoids, as put forth in the declaration, the extract does have some efficacy with respect to anti-inflammatory, anti-mutagenic and anti-microbial conditions.

Further, the hydroalcoholic extract claimed in claim 1 (and therefore, in claim 3) has a high amount of curcuminoids. As detailed in paragraph no. 11 of the declaration, the amount of curcuminoids present in a crude extract may be 25-30%. However, the curcuminoid amount in the enriched product of the '415 patent is upwards of 90% in the extract. The hydroalcoholic extract product of the '415 patent is a powder with a melting range of 180-185°C, while the supercritical extract is a clear liquid.

Therefore, Applicants respectfully submit that there are clear differences between the supercritical extract of turmeric and the hydroalcoholic extract of turmeric, and that the '415 patent only discloses the hydroalcoholic extract of turmeric. Thus, the '415 patent fails to disclose the supercritical extract of turmeric and the Examiner has filed to prove a prima facie case of anticipation since all of the claimed limitations of claims 1 and 3 are not shown in the '415 patent. As such, the '415 patent does not anticipate the claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims as being anticipated by the '415 patent.

3. Rejection of Claim 5

Under 35 U.S.C. 103(a)

Claim 5 stands rejected under 35 U.S.C. 103(a) as being obvious over Majeed et al. (U.S. Patent No. 5,861,415, "the '415 patent") and "Antioxidant Effects of Tea" (page 249-254) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The references of record do not teach or suggest Applicants' inventive subject matter as a whole, as recited in the rejected claims. Further, there is no teaching or suggestion in these references which would lead the ordinary skilled artisan to modify the references to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the

claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974. Applicants respectfully submit that the Examiner has failed to prove this.

Claim 5 depends from claim 1 and contains all of the limitations found in claim 1. Thus, if claim 1 is not obvious over the combination of references, then neither is claim 5. As indicated above, Claim 1 is directed to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric.

Applicants argued that claim 1 (and 3) is not anticipated by the '415 patent based on the differences between the two extracts, differences which are not present in the '415 patent. The arguments made above with respect to the anticipation rejection are hereby incorporated into this response. In particular, Applicants submit that, based on Dr. Quirin's declaration, the curcuminoids shown at the top of column 2 of the '415 patent are **not** present in the supercritical extract at a concentration to provide efficacy to the composition. The curcuminoids are present in the hydroalcoholic extract, but not the supercritical extract.

Applicants submit that, since the '415 patent is concerned with the purification of curcuminoids found in the hydroalcoholic extract of turmeric, there is no motivation or teaching within the '415 patent to include a supercritical extract of turmeric in a composition containing a hydroalcoholic extract of turmeric. Since the amount of curcuminoids present in the supercritical extract are negligible, one of ordinary skill in the art would not be lead by the '415 patent to combine a supercritical extract with a hydroalcoholic extract in an attempt to achieve present claim 1 (and therefore claim 5). Further, Applicants submit that these limitations are also missing from the "Antioxidant" article relied upon by the Examiner. Thus, a combination of the '415 patent and the article would **not** achieve the present claims.

Applicants have shown that a combination of the '415 patent and the "Antioxidant" article fails to teach all of the claimed limitation, and there is no motivation to modify the references in an attempt to do so. Thus, Applicants submit that the Examiner has failed to prove a prima facie case of obviousness with respect to claim 5.

Accordingly, Applicants respectfully submit that the claims are unobvious over the combination of references, and respectfully request reconsideration and withdrawal of this rejection.

4. Rejection of Claims 1-12

Under 35 U.S.C. 103(a)

Claims 1-12 stand rejected as being obvious over the Oppenheim reference (WO 99/20289, "the '289 reference") in view of "Antioxidant Effects of Tea" (page 249-254) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The references of record do not teach or suggest Applicants'

inventive subject matter as a whole, as recited in the rejected claims. Further, there is no teaching or suggestion in these references which would lead the ordinary skilled artisan to modify the references to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial

burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974. Applicants respectfully submit that the Examiner has failed to prove this.

Claim 1 is directed to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric. Likewise, claim 8 is an independent claim that also contains the limitation of including supercritical and hydroalcoholic extracts of turmeric. The remaining claims depend from these independent claims, and therefore necessarily contain all of the limitations found therein. Thus, if the independent claims are unobvious over the references, then so, too, are the dependent claims.

Applicants respectfully submit that the '289 reference does not teach, nor suggest, the claimed combination of supercritical and hydroalcoholic extracts of turmeric. As discussed above with respect to the other rejections (said discussions being incorporated here by reference), there is considerable differences between the two turmeric extracts, namely that curcuminoids are found in the hydroalcoholic extract and not the supercritical extract. Applicants respectfully submit that the '289 reference does not teach a composition comprising the combination of supercritical extracts and hydroalcoholic extracts.

The '289 reference teaches extraction techniques generally.

The reference teaches extracting turmeric by solvent extraction, as indicated on page 9, lines 24-30, where turmeric is listed as an herb which has been extracted and dissolved in a hydrophilic fill. Further, example 5 on page 14 of the reference deals with the hydrophilic extraction of turmeric.

However, Applicants respectfully submit that the '289 reference fails to teach the supercritical extraction of turmeric, as well as a composition comprising a supercritical extract and hydroalcoholic extract of turmeric, as presently claimed. Further, there is no motivation or teaching within the '289 reference to modify it to achieve the presently claimed inventive subject matter. The subject matter of the '289 reference is directed to the encapsulation of herb solutions wherein the herb is concentrated and unsuitable for encapsulation without a suitable fill. Thus, the reference is concerned with matching the herb extract with a hydrophilic or hydrophobic fill material so that the herb is able to be encapsulated. This is wholly different than the claimed subject matter of a composition comprising a mixture of two different extracts of turmeric. One of ordinary skill in the art would not be lead by the '289 reference to combine a supercritical extract and a hydroalcoholic extract of turmeric in an attempt to achieve the claimed subject matter.

In addition, the deficiencies of the '289 reference are not

remedied by the "Antioxidant" article. The article does not disclose the missing limitations, and therefore, one of ordinary skill in the art would not achieve the present claims by combining the two references.

Applicants have shown that a combination of the '289 reference and the "Antioxidant" article fails to teach all of the claimed limitation, and there is no motivation to modify the references in an attempt to do so. Thus, Applicants submit that the Examiner has failed to prove a prima facie case of obviousness with respect to claims 1-12.

Accordingly, Applicants respectfully submit that the claims are unobvious over the combination of references, and respectfully request reconsideration and withdrawal of this rejection.

5. Rejection of Claims 1-12

under Obviousness-Type Double Patenting

Claims 1-4 stand rejected under the doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,391,364 (sic) and over claim 1 of U.S. Patent No. 6,264,995, for the reasons set forth in the office action.

RESPONSE

Applicants respectively traverse these rejections and request reconsideration and withdrawal thereof.

As an initial matter, Applicants note the incorrect patent no. with respect to the first double patenting rejection. The Office Action states that claims 1-4 stand rejected under obviousness-type double patenting over claim 1 of U.S. Patent No. 6,391,**364**. During the interview, the Examiner indicated that the correct patent no. should be 6,391,**346**. Applicants traverse the rejection of the claims over this patent.

The claims are rejected under the judicially-created doctrine of obviousness-type double patenting. Applicants respectfully traverse these rejections on the basis that claims 1-4 are not obvious over claim 1 of the '346 patent, nor claim 1 of the '995 patent.

Claim 1 is directed to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric. Claims 2-4 depend from claim 1, and therefore necessarily contain all of the limitations found therein. Thus, if the independent claim is unobvious over the references, then so, too, are the dependent claims.

Applicants respectfully submit that claim 1 of either the '346

patent or the '995 patent does not teach, nor suggest, the claimed combination of supercritical and hydroalcoholic extracts of turmeric. As discussed above with respect to the other rejections (said discussions being incorporated here by reference), there is considerable differences between the two turmeric extracts, namely that curcuminoids are found in the hydroalcoholic extract and not the supercritical extract. Applicants respectfully submit that claim 1 of either reference does not teach a composition comprising the combination of supercritical extracts and hydroalcoholic extracts of turmeric.

Claim 1 of the '346 patent claims only a hydroalcoholic extract of turmeric. There is no mention or inclusion of a supercritical extract of turmeric, nor, for the reasons indicated above, would one of ordinary skill in the art be lead to a composition of **both** a hydroalcoholic extract and a supercritical extract of turmeric by reading claim 1 of the '346 patent.

Likewise, claim 1 of the '995 patent includes an alcoholic, aqueous, a hydroalcoholic **or** a supercritical extract of turmeric. There is no guidance or teaching within the patent or claim to lead one of ordinary skill in the art to prepare a composition with **both** a hydroalcoholic extract and a supercritical extract of turmeric.

Thus, the claimed limitations of present claims 1-4 are not obvious over claim 1 of the '346 and '995 patents. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-4 under the judicially created doctrine of obviousness-type double patenting.

CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,
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